IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

BRENDA PARRISH, Individually, and as Administratrix of the Estate of KYLE J. PARRISH, Plaintiff, v. MEDTRONIC USA, INC., ET AL., Defendants.	CASE NO: 1:19-CV-02995 JUDGE JAMES S. GWIN **ORAL ARGUMENT REQUESTED**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT

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INTRODUCTION AND SUMMARY OF THE ARGUMENT

This lawsuit allegedly relates to a ventricular assist medical device system, which is prescribed for patients with severe heart failure, often as they await a heart transplant. Kyle Parrish ("Decedent") allegedly was using a ventricular assist device (the "VAD") manufactured and sold by Medtronic USA, Inc. ("Medtronic USA"), Medtronic, Inc. ("Medtronic"), and Heartware International Inc. ("Heartware") [collectively, "Defendants"] at the time of his death on November 27, 2017. Brenda Parrish ("Plaintiff"), the administratrix of his estate, asserts causes of action for wrongful death and products liability against Defendants, alleging that Decedent's VAD was defective or malfunctioned. Defendants deny that they are liable to Plaintiff, and deny that they, or the VAD, caused or contributed to Decedent's death.

Plaintiff's Complaint and all of her claims and causes of action against Defendants are subject to dismissal for four primary reasons.

First, Plaintiff's claims are expressly and/or impliedly preempted by federal law. The VAD allegedly at issue is a Class III medical device that was approved by the United States Food & Drug Administration ("FDA") pursuant to the rigorous Premarket Approval process. Consequently, any claim that seeks to impose a requirement that is different from or in addition to the applicable federal requirements is expressly preempted by the Medical Device Amendments to the Food, Drug, and Cosmetic Act ("FDCA"), as interpreted by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). Because Plaintiff's claims would require a jury to determine that Defendants should have designed, manufactured, and labeled the device at issue in a manner different from the design, manufacture, and labeling approved by FDA, Plaintiff's claims are preempted as a matter of law. To the extent Plaintiff alleges Defendants withheld information

from the FDA, those claims are impliedly preempted in accordance with the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 343 (2001).

Second, Plaintiff has not asserted plausible claims that are sufficient to survive a motion to dismiss. Plaintiff fails to identify the specific medical device that is the subject of her claims, and fails to allege how it was defective or allegedly caused damages. Instead, all of Plaintiff's allegations are conclusory and fail to differentiate between Defendants.

Third, to the extent Plaintiff has attempted to assert common law claims, they are abrogated by the Ohio Products Liability Act (the "OPLA"), which is Plaintiff's exclusive remedy for product liability claims. Fourth, and finally, Plaintiff's claims for wrongful death and punitive damages under Ohio law fail for various reasons. Accordingly, Defendants respectfully submit that Plaintiff's Complaint should be dismissed in its entirety.

STATEMENT OF RELEVANT FACTS

I. FACTS ALLEGED BY PLAINTIFF

Plaintiff's bare-bones Complaint lacks factual detail. Plaintiff alleges that Decedent died on November 27, 2017. (*Id.* ¶ 3.) Plaintiff asserts that a ventricular assist medical devices and accessories caused Decedent's death. (*Id.* ¶ 11.) Plaintiff alleges that Defendants collectively designed, manufactured, and distributed the unspecified medical devices at issue. (*Id.* ¶ 11.) Plaintiff also vaguely alleges that the device was "defective, malfunctioned, or otherwise failed in a manner contemplated" by a Class I recall that occurred in May 2018 (following Decedent's death) (*Id.* ¶ 12), but does not specify the nature of the issue alleged to have occurred in this case. Among other important facts, Plaintiff does not specify: what medical device is the subject of Plaintiff's claims; what condition necessitated the prescription for the device at issue; who prescribed the device for Decedent; when or by whom Decedent was implanted with the device;

how the device was defective or malfunctioned; nor how the alleged defect caused Decedent's death and Plaintiff's injuries.

II. STATUTORY AND REGULATORY BACKGROUND.

In 1976, Congress enacted the MDA, 21 U.S.C. §§ 360c *et seq.*, which granted the FDA the exclusive authority to regulate medical devices, creating a comprehensive "regime of detailed federal oversight." *Riegel*, 552 U.S. at 316. Congress also specified that no state may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable…to the device" under federal law. 21 U.S.C. § 360k(a).

A. The Rigorous Premarket Approval Process for Class III Devices

Under the MDA, different types of devices receive different levels of scrutiny from FDA. Devices that "support or sustain human life" or "present a potential unreasonable risk of illness or injury" are designated "Class III" devices. 21 U.S.C. §360c(a)(1)(C)(ii). A Class III device must receive FDA's Premarket Approval ("PMA") before it may be brought to market, and "incur[s] the FDA's strictest regulation." *Buckman*, 531 U.S. at 343. The PMA process is the most exacting form of FDA review for medical devices. Obtaining "[p]remarket approval is a 'rigorous' process." *Riegel*, 552 U.S. at 317 (internal citations omitted). FDA "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* (quoting 21 U.S.C. §360e(d)). To obtain FDA's PMA approval, a manufacturer:

> must submit a detailed PMA application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information.

Riegel v. Medtronic, Inc., 451 F.3d 104, 109 (2d Cir. 2006) (citing 21 U.S.C. § 360e(c)), *aff'd*, 552 U.S. 312 (2008).

FDA closely and rigorously scrutinizes PMA applications, "'weigh[ing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). This review is lengthy, taking an average of 1200 hours per application. *Id.* In addition to its own review, FDA may refer the application to a panel of outside experts. *See id.* (citing 21 C.F.R. § 814.44(a)). As part of the PMA process, FDA must review a device's proposed labeling to "evaluate[] safety and effectiveness under the conditions of use set forth on the label," and "determine that the proposed labeling is neither false nor misleading." *Id.*, § 360e(d)(1)(A)). If FDA decides a device's design, manufacturing methods, or labeling should be revised, it can require revisions before approval. *See id.* at 319 (citing 21 C.F.R. § 814.44(e)). The content of the labeling, including all warnings, representations, and other information therein or omitted therefrom, are all specified by FDA through its regulations and its line-by-line review during the PMA process.[1] *See id.*

B. The FDA Exclusively Enforces Class III Device Requirements

Congress has specified that all actions to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Although "citizens may report wrongdoing and petition the agency to take action," *Buckman*, 531 U.S. at 349 (citing 21 C.F.R. § 10.30), there is no private right of action under the FDCA. *Id.* at 349, n.4. Rather, "[t]he United States has exclusive authority to enforce the [FDCA's] provisions." *See* Brief for the United States as *Amicus Curiae*, *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008), No. 06-1498, 2007 WL 4218889, at *4 (Nov. 28,

[1] FDA's regulatory role does not end with approval of the initial PMA application. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). If a manufacturer wishes to make such changes, it must submit a PMA Supplement and can implement the proposed changes only after FDA approval. *See Riegel*, 451 F.3d at 110 (citing 21 C.F.R. § 814.39(a)). A PMA Supplement is subject to the same rigorous standards of review as an initial PMA application. *Riegel*, 552 U.S. at 319 (citing 21 C.F.R. § 814.39(c)); *see also Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000).

2007). Consistent with its exclusive power to enforce the FDCA, FDA has the authority to investigate violations of the MDA, "and to pursue a wide range of sanctions for any fraud it uncovers." *Id.* at *3 (citation omitted).

C. PMA Approval of the Medical Device at Issue

Although Plaintiff does not identify the allegedly defective device with any specificity, it appears that Plaintiff's claims relate to the HeartWare VAD system. (*See, e.g.*, Compl. ¶ 9 ("All named Defendants are engaged in the manufacture, marketing, sale and distribution of ventricular assist medical devices along with related accessories and services"); ¶ 11 ("All named Defendants sold, marketed and/or distributed ventricular assist medical device(s) and/or batteries(s)[sic] and/or ventricular assist medical device power system(s) and/or battery recharging systems(s)[sic] and/or accompanying equipment/accessories/component parts used by Plaintiff Kyle Parrish")). The VAD is a prescription medical device system indicated for use as a bridge to cardiac transplantation in patients who are at risk of death due to refractory end-stage left ventricular heart failure. The VAD consists of several components, including a monitor, implantable centrifugal blood pump, AC adapter, external controller, and batteries.

As set forth on the FDA's website, the VAD is a Class-III medical device approved by FDA through the rigorous PMA process. Medtronic initially submitted a premarket approval application, P100047, for the VAD on December 28, 2010, which the FDA approved on November 20, 2012. (*See* Premarket Approval #P100047, Exh. A).[2] Since that time, the FDA has approved

[2] Information regarding FDA's PMA approval of the VAD (PMA # P100047) and its supplements may be viewed by searching for PMA Number "P100047" and Decision Date "11/20/2012" to "11/20/2012" in the Premarket Approval database on the FDA's website at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm (last viewed on January 20, 2020). For the Court's convenience, true and correct copies of the PMA database entry for P100047 and the November 20, 2012 Premarket Approval are attached as Exhibit A. This Court may take judicial notice of the FDA's PMA approval, supplements, and related FDA documents available on the FDA website because they are public government records that are not subject to reasonable dispute. *See* Fed. R. Evid. 201(b)(2);

over 100 supplements to Medtronic's original premarket approval. (*Id.*) Accordingly, no matter which model is at issue, the device is a Class III prescription medical device approved through the FDA's rigorous PMA process.

D. The May 2018 Recall Involving the Device at Issue

Plaintiff claims that the "Products were found to be defective, malfunctioned or otherwise failed while in use by Plaintiff Kyle Parrish, such devices were subject to Class I recalls to specifically include Class I recall by the FDA on May 2, 2018." (Compl. ¶ 12.)[3] The Recall was initiated by Heartware on May 2, 2018, and posted by FDA on May 21, 2018. (Recall, Exh. B). The Recall notified physicians and healthcare professionals about a possible issue of 1-2 second electrical interruption between an VAD system power source and the controller, which "may cause unintended switching to the secondary power source and/or unexpected audible tones (beeping)." (*Id*.) Clinicians were also informed about a field service for application of a lubricant to mitigate the potential for electrical interruptions. (*Id.*) The Recall did not require that clinicians stop using or return affected products. (*Id.*)

LEGAL STANDARD

To state a claim for relief, a pleading must contain a short and plain statement of the claim showing that the pleader is entitled to relief. Fed. R. Civ. P. 8(a)(2). To survive a motion to dismiss

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Jones v. City of Cincinnati, 521 F.3d 555, 562 (6th Cir. 2008) ("A court may consider public records without converting a Rule 12(b)(6) motion into a Rule 56 motion."); *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1014 (S.D. Ohio 2016) (taking judicial notice of FDA documents, including Premarket Approval and device labeling, on motion to dismiss).

[3] Plaintiff does not attach a copy of the referenced recall, but a copy of the May 21, 2018 recall (the "Recall") is publicly available on the FDA's website at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=164298 (last viewed on January 20, 2020). A true and correct copy of the Recall is attached hereto as Exhibit B. As set forth above, this Court may take judicial notice of the Recall available on the FDA website because it is a public government record is not subject to reasonable dispute. *See* Fed. R. Evid. 201(b)(2); *see also Jones*, 521 F.3d at 562; *Aaron*, 209 F. Supp. 3d at 1014.

under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter . . . to 'state a claim . . . that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). While Rule 8 "does not require 'detailed factual allegations,' . . . it demands more than an unadorned, the-defendant-unlawfully-harmed me accusation." *Id.* (quoting *Twombly*, 550 U.S. at 555). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citation omitted). The plaintiff must "nudge" his claims "across the line from conceivable to plausible" to avoid dismissal. *Twombly*, 550 U.S. at 570. The plausibility standard requires "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556).

ARGUMENT

I. PLAINTIFF'S CLAIMS ARE PREEMPTED UNDER FEDERAL LAW

Plaintiff's claims are preempted by federal law. As best Defendants can discern, the medical device at issue is the VAD, a Class III medical device. Accordingly, its design, construction, manufacturing, and labeling were all specifically reviewed and approved by the FDA pursuant to the PMA process. As Plaintiff's claims attack the design, manufacturing processes, warning labeling, or other aspects of the device, they are all expressly preempted by the MDA, 21 U.S.C. § 360k(a), as interpreted by the Supreme Court in *Riegel*, 552 U.S. 312, and subsequently held by a multitude of federal and state courts across the country. Additionally, to the extent Plaintiff's claims are based on Defendants' alleged withholding of information concerning the subject device from the FDA (*see* Compl. ¶ 13), any such claims are preempted by 21 U.S.C. § 337(a), which provides that all actions to enforce the FDCA "shall be by and in the name of the United States," as interpreted by the Supreme Court in *Buckman*, 531 U.S. at 349.

A. Plaintiff's Claims Are Expressly Preempted

The issue of federal preemption is a question of law that can be resolved on a motion to dismiss under Rule 12(b)(6). *See, e.g., Riegel*, 451 F.3d at 107. In *Riegel*, the plaintiff brought a personal injury suit against Medtronic, the manufacturer of a Class III PMA-approved balloon catheter that allegedly ruptured during the plaintiff's angioplasty procedure. The plaintiff asserted state law products liability claims, including strict liability, breach of implied warranty, and negligence. *See Riegel*, 552 U.S. at 312. The Supreme Court held that each state law claim was expressly preempted. *Id.* at 322-23, 330. The *Riegel* Court explained the MDA preemption clause establishes a two-step procedure for determining if state law claims are expressly preempted. First, a court must determine whether "the Federal Government has established requirements applicable to" the particular medical device. *Id.* at 321. If it has, then the court must determine whether the state law claims would impose "requirements with respect to the device that are 'different from, or in addition to'" the federal requirements that relate to either (i) "safety or effectiveness" or (ii) "any other matter included in a requirement applicable to the device [under 21 U.S.C.] § 360k(a)." *Id.* at 321-23. If both conditions are satisfied, then the claim is expressly preempted. Claims involving a PMA-approved Class III device, such as the VAD, "automatically satisfy the first prong of the *Riegel* test." 552 U.S. at 322-23; *accord Warstler v. Medtronic, Inc.*, 238 F. Supp. 3d 978, 986 (N.D. Ohio 2017).

As for the second condition of the express preemption test, *Riegel* held that state common law duties constitute "requirements," and "the duties underlying negligence, strict-liability, and implied-warranty claims" are requirements "with respect to devices." *Id.* at 324, 327. *Riegel* explicitly rejected the proposition that, to be expressly preempted, a common-law duty "must apply *only* to the relevant device," or even "only to medical devices and not to all products and all actions in general." *Id*. at 328. Thus, *Riegel* stands unequivocally for the proposition that statutory or

common law causes of action that would impose a state-law duty "different from, or in addition" to those imposed by the FDA through its Premarket Approval of a device (21 U.S.C. § 360k(a)) are expressly preempted by the MDA. The Court found:

> in the context of [the MDA] excluding common-law duties from the scope of pre-emption would make little sense. State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.

Riegel, 552 U.S. at 324-25.

Since *Riegel* was decided, "courts across the country have applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence, to breach of warranty, to failure to warn and manufacturing-and-design-defect, to negligence per se." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009), *aff'd,* 623 F.3d 1200 (8th Cir. 2010) ("*In re Medtronic, Inc*."). In case after case, state and federal courts, including in the Sixth Circuit and courts in this District, have applied *Riegel* to reject state law claims seeking to impose different or additional requirements on PMA-approved medical devices. *See, e.g., Kemp v. Medtronic, Inc.*, 231 F.3d 216, 237 (6th Cir. 2000) (affirming preemption of claims involving Class III devices); *Wilhite v. Howmedica Osteonics Corp*., 833 F. Supp. 2d 753 (N.D. Ohio June 20, 2011) (all claims related to Class III PMA-approved device

preempted); *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994 (S.D. Ohio 2016) (strict liability, negligence, and breach of warranty claims preempted).[4]

Plaintiff asserts wrongful death and product liability claims that allege defects in the design and formulation, manufacture and construction, warnings or instruction, and because the device did not conform to the representations made by Defendants. (*See, e.g.*, Compl. ¶¶ 11, 12, 16, 18-28.) Congress has expressly precluded state law tort claims, such as those asserted here, that seek to challenge the safety and effectiveness of the design, manufacture, or labeling of a Class III medical device previously approved by the FDA via the PMA process. Such claims necessarily require a jury to invade the exclusive province of the FDA by substituting its judgment for that of the federal agency commissioned with the expertise and authority to govern these devices. The FDA regulates the design and manufacturing of Class III medical devices and the FDA's Premarket Approval is a conclusive, preemptive determination that there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 317 (quoting 21 U.S.C. § 360e(d)). Like the claims in *Riegel*, Plaintiff's products liability claims clearly are based on the VAD's safety and effectiveness and therefore are preempted. *See, e.g., Anderson v. Boston Scientific Corp*., No. 1:12-CV-00762, 2013 U.S. Dist. LEXIS 22982, at *13-14 (S.D. Ohio Feb.

[4] *See also Otis-Wisher v. Medtronic, Inc.*, 616 F. App'x 433, 434 (2d Cir. 2015) (strict liability failure to warn, strict liability design defect, and negligent failure to warn claims expressly preempted); *Wolicki-Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1301-03 (11th Cir. 2011) (strict liability manufacturing and design defect, failure to warn, and negligence claims preempted); *Walker v. Medtronic, Inc*., 670 F.3d 569 (4th Cir. 2012) (negligence, strict liability, and breach of warranty claims preempted); *In re Medtronic, Inc.*, 623 F.3d at 1209 (affirming dismissal of all claims in the Sprint Fidelis MDL as preempted); *Hawkins v. Medtronic, Inc*., No. 1:13-cv-00499, 2014 U.S. Dist. LEXIS 11779 (E.D. Cal. Jan. 30, 2014) (granting motion to dismiss on all claims including failure to warn, strict design defect, misrepresentation, and negligence); *Dawson v. Medtronic, Inc.* No. 3:13-cv-00663-JFA, 2014 U.S. Dist. LEXIS 3306 (D.S.C. Jan. 6, 2014) (dismissing all claims with prejudice); *McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1201 (M.D. Fla. 2013) (holding plaintiff's state law claim for negligence was expressly and impliedly preempted); *Cooley v. Medtronic, Inc.*, No. 09-30-ART, 2012 U.S. Dist. LEXIS 55878 (E.D. Ky. Apr. 20, 2012) (motion to dismiss based on preemption granted on all claims involving implantable cardiac defibrillator, including express warranty, fraud, and emotional distress).

20, 2013) (all products liability claims related to Class III device were preempted); *Wilhite*, 833 F. Supp. 2d at 763 (same); *Anthony v. Stryker Corp*., 1:09–cv–2343, 2010 U.S. Dist. LEXIS 1387790 (N.D. Ohio Mar. 31, 2010) (strict liability and negligence claims preempted); *In re Sulzer Hip Prosthesis and Knee Prosthesis Liab. Litig.*, 455 F. Supp. 2d 709, 720 (N.D. Ohio 2006) (plaintiffs' claims for design defect and manufacturing defect preempted under the MDA).[5]

Plaintiff's claims are also preempted to the extent they attack the sufficiency of the warnings and representations accompanying the VAD. (*See, e.g.*, Compl. ¶¶ 16, 18, 20, 21, 25-27). FDA meticulously reviews, edits, and mandates all warning information for Class III medical devices during the PMA process, including all packaging, product literature, manuals, instructions and marketing materials, collectively referred to as "labeling." *See Riegel*, 552 U.S at 318 (citing 21 C.F.R. §§ 360c(a)(2)(B), 360e(d)(1)(A)). The manufacturer must label, market, and distribute the device "with almost no deviations from the specifications in its [premarket] approval application." *Id*. (citing 21 C.F.R. § 360c(a)(2)(B)). Plaintiff contends that the device possessed unspecified deficiencies in its warnings or instructions. (*See, e.g.*, Compl. ¶¶ 16, 18, 20, 21, 25-27). Essentially, Plaintiff attempts to require Defendants to provide additional or different warnings that would impose state law requirements beyond those set by federal law. *See In re Medtronic, Inc.*, 592 F. Supp. 2d at 1160-61. Regardless of whether Plaintiff's products liability claims are characterized as attacking the design, manufacturing, or the warnings of the VAD, all her claims are preempted pursuant to *Riegel* and should be dismissed.

[5] As explained more fully below, Plaintiff has not pleaded a plausible claim. To the extent Plaintiff contends that the PMA-approved design specifications or manufacturing process should have been different (*see, e.g.*, Compl. ¶¶ 12, 18-19, 22-24), that claim fails because any such claim would be "different from, or in addition to" federal requirements. *See Riegel*, 552 U.S. at 321.

B. Plaintiff's Claims Are Otherwise Preempted

To the extent Plaintiff seeks to hold Defendants liable for "willfully and knowingly with[holding] knowledge of the defect, malfunction or failure from the FDA in direct violation of federal law including but not limited to Section 513(a) of the [FDCA]," (Compl. ¶ 13; *see also id.* ¶ 28), those claims are also impliedly preempted. In *Buckman*, the Supreme Court held that state law claims based on fraud-on-the-FDA theories "conflict with, and are therefore impliedly pre-empted by, federal law" because they "inevitably conflict with the FDA's responsibility to police fraud consistently with the [FDA's] judgment and objectives." 531 U.S. at 348, 350. *Buckman* made clear that although "citizens may report wrongdoing and petition the agency to take action," *id.* at 349 (citing 21 C.F.R. § 10.30), under 21 U.S.C. § 337(a), "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance." *Id.* at 349, n.4. In reaching this conclusion, the Supreme Court reasoned that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives," a balance which is skewed if state law fraud-on-the-FDA claims are allowed. *Id.* Thus, under *Buckman*, federal law impliedly preempts claims based solely on violations of FDA requirements. *Id.* at 348. As applied here, to the extent Plaintiff's claims are based on alleged failure to warn FDA, they are also impliedly preempted and should be dismissed.

II. THE COMPLAINT FAILS TO SATISFY THE REQUISITE PLEADING STANDARDS.

Plaintiff's claims also fail under Rule 8 because she has failed to allege several necessary facts including the medical device at issue, the specific defect in the design, manufacture, or labeling of the medical device, and how that unidentified defect caused Plaintiff's alleged damages. Those failures compel the dismissal of Plaintiff's claims.

A. The Complaint Fails to Identify the Medical Device at Issue

The Complaint is replete with conclusory, boilerplate allegations and contains few, if any, concrete factual allegations concerning the specific medical device allegedly at issue; it also fails to allege when or by whom the device was prescribed. Instead, Plaintiff vaguely refers to "ventricular assist medical devices along with related accessories." (Compl. ¶ 9; *see also id.* ¶ 11 ("ventricular assist medical device(s) and/or batteries(s) [sic] and/or ventricular assist medical device power system(s) and/or battery recharging systems(s) and/or accompanying equipment/accessories/component parts"). Plaintiff's failure to identify the device at issue is incompatible with Ohio law. *See Baldwin v. Zimmer*, No. 2:10-cv-01144, 2011 U.S. Dist. LEXIS 92850, at *5-6 (S.D. Ohio Aug. 19, 2011) (dismissing claims where court was unable to discern which medical device was at issue); *see also Jackson v. Glidden Co.*, 2007-Ohio-277, 2007 Ohio App. LEXIS 268, ¶ 28 (Ohio Ct. App. Jan. 25, 2007) (inability to identify the specific product or manufacturer at issue defeated tort claim); Ohio Rev. Code § 2307.73(A)(3) (incorporating identification requirement in OPLA because plaintiff must prove defendant's responsibility for "the actual product that was the cause of harm for which the claimant seeks to recover.").

A "plaintiff armed with nothing more than conclusions" is not entitled to "unlock the doors of discovery." *Iqbal*, 566 U.S. at 678-79. Plaintiff's failure to plead basic facts concerning the device allegedly at issue would require Defendants to engage in significant discovery merely to begin to evaluate the basis of Plaintiff's claims. There is no excuse for Plaintiff's generic pleading, and the Court should dismiss Plaintiff's claims in their entirety.

B. The Complaint Fails to Distinguish Between the Defendants

Plaintiff refers to "Defendants" collectively throughout the Complaint, and makes no effort to articulate which conduct is allegedly attributable to each entity. By failing to distinguish between Defendants, Plaintiff fails to give each Defendant sufficient notice of the acts or omissions

for which it is allegedly responsible. The Complaint is subject to dismissal for this reason alone. *See, e.g.*, *Kurek v. Ohio Dep't of Developmental Disabilities, Inc.*, No. 3:16-cv-623, 2017 U.S. Dist. LEXIS 65473, at *15-16 (N.D. Ohio Jan. 20, 2017) ("[C]onclusory allegations of collective, unspecified, and undifferentiated wrongdoing is not sufficient: vaguely lump[ing] all defendants together without providing any factual allegations that specify separate acts fails to satisfy the *Iqbal/Twombly* standard.") (internal quotations omitted; citing cases).[6]

C. The Complaint Fails to State a Plausible Claim Under the OPLA

To the extent Plaintiff's products liability claim (Count II) can be construed as asserting a claim under the OPLA, it should be dismissed because Plaintiff has failed to specify the OPLA provisions under which her claim is sought,[7] and because Plaintiff's conclusory allegations fail to state a claim under any cognizable theory of liability.[8] Under the OPLA, a manufacturer is liable for compensatory damages only where the plaintiff establishes the following:

> (1) . . . the manufacturer's product in question was defective in manufacture or construction as described in section 2307.74 of the Revised Code, was defective in design or formulation as described in section 2307.75 of the Revised Code, was defective due to inadequate warning or instruction as described in section 2307.76 of the Revised Code, or was defective because it did not conform to a representation made by its manufacturer as described in section 2307.77 of the Revised Code; (2) [a] defective aspect of the manufacture's product in question . . . was a proximate

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[6] The Complaint also improperly purports to incorporate all prior allegations in each successive cause of action. (*See* Compl. ¶¶ 15, 31.) This type of "shotgun pleading" compounds the confusion in Plaintiff's Complaint and has been rejected by courts in this Circuit. *See, e.g.*, *Lasson v. Brannon & Assocs. Attys. at Law*, No. 3:07-cv-0271, 2008 U.S. Dist. LEXIS 117893, at *10 (S.D. Ohio Jan. 30, 2008), *report and recommendation adopted*, 2008 U.S. Dist. LEXIS 11493 (Feb. 15, 2008).

[7] "Claims that are authorized by the OPLA should be pled with reference to the applicable provision of the OPLA." *Boroff v. Alza Corp.*, 685 Supp. 2d 704, 709 (N.D. Ohio 2010) (citation omitted); *see also Lorenzo v. Bristol-Myers Squibb Co.*, No. 1:12-cv-00754, 2012 U.S. Dist. LEXIS 105518, at *7 (N.D. Ohio July 30, 2012) ("When bringing claims under the OPLA, plaintiffs should clarify which OPLA provision governs the claims in their complaint") (citation omitted).

[8] Plaintiff does not state whether her claims are based on strict liability or negligence theories. Regardless, both negligence claims and strict liability claims are preempted under *Riegel*. Plaintiff's failure to distinguish between these theories of liabilities, and her failure to distinguish amongst Defendants and their respective roles with respect to the VAD, further underscores the inadequacy of her pleading.

> cause of harm for which the claimant seeks compensatory damages; [and] (3) [t]he manufacturer designed, formulated, produced, constructed, created, assembled, or rebuilt the actual product that the was cause of the harm for which the claimant seeks to recover compensatory damages.

Ohio Rev. Code § 2307.73.

Plaintiff fails to plead any of those elements, and instead offers bare legal conclusions unsupported by factual allegations. Plaintiff fails to specify which device is the subject of her claims, and fails to specify how the device was allegedly defective (i.e., why the device is dangerous, how it failed to perform in the reasonably expected manner, how it deviated from other identical devices, or how the attendant warnings were inadequate).[9] Plaintiff also fails to provide any factual allegations that connect the VAD to the alleged damages and merely asserts legal conclusions. For example, Plaintiff alleges:

- "Defendants failed to exercise reasonable care in the design, testing, manufacture, construction, marketing, product warning and or modification of the Products to assure that it was safe for its intended use." (Compl. ¶ 18.)

- "Defendants maliciously, recklessly and negligently failed to exercise reasonable care in warning consumers, to include the Plaintiff, of the risks, dangers and/or defects of said Products, as they knew or should have known the defects and inherent dangers of said Products." (*Id.* ¶ 20.)

- "Defendants' aforementioned Products [sic] . . . was defective in testing, manufacture, formulation, and/or design that when said Products [sic] left the hands and control of these Defendants, it deviated materially from the industry standards, and/or differed from otherwise identical units manufactured to the same design formula and/or specifications." (*Id.* ¶ 22.)

- "Defendants' Products [sic] . . . was defective in design and/or formulation in that, when it left the hands and control of these Defendants, the foreseeable risk of harm i.e., malfunctioning and/or catastrophic explosion of these Defendants' aforementioned Products associated with the design and/or formulation, exceeded its benefits." (*Id.* ¶ 23.)

[9] Although Plaintiff alleges, in conclusory fashion, that the device was defective in the manner contemplated by the Recall (Compl. ¶ 12), Plaintiff provides no factual allegations supporting that conclusory assertion or that the device at issue actually suffered from any transient electrical connection disruption between the power source and controller. (*See generally*, the Recall, Exh. B.)

- "As a direct and proximate result of the defective condition of these Defendants' Products which were manufactured, designed, tested, modified, marketed and/or distributed by these Defendants, and the tortious conduct of these Defendants, Plaintiff sustained serious personal injuries . . . ." (*Id.* ¶ 30.)

Allegations like these, devoid of any factual underpinnings or contentions, are routinely dismissed for failure to allege a plausible claim. *See, e.g., Liming v. Stryker Corp.*, No. 1:11–cv–788, 2012 U.S. Dist. LEXIS 75509, at *13 (S.D. Ohio May 31, 2012) (dismissing design defect claim because the complaint "merely regurgitates, nearly verbatim, the elements of a defective design claim ... [and] contains no substantive, specific factual allegations with respect to the design of the pain pump from which the Court could plausibly infer a strict liability design defect cause of action"); *Baldwin,* 2011 U.S. Dist. LEXIS 92850 at *5-6 (dismissing claims where plaintiffs failed to specially identify the defects at issue); *Frey v. Novartis Pharma. Corp.*, 642 F. Supp. 2d 787, 795 (S.D. Ohio 2009) (dismissing design defect claim "because plaintiffs have once again simply provided a formulaic recitation of the elements . . ." and "have not alleged any facts that would permit the Court to conclude that there was a defect in the design or formulation").

Additionally, to the extent Plaintiff's claim is based on a failure to adequately warn her or the Decedent, it fails because medical device manufacturers do not have a duty to warn a patient directly. The OPLA incorporates the learned intermediary doctrine, providing that:

> An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the [FDA] has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

Ohio Rev. Code § 2307.76(C). The Ohio Supreme Court has applied the same rationale to medical devices. *See Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 164-65 (2002); *see*

also Yanovich v. Zimmer Austin, Inc., 255 Fed. App'x 957, 970 (6th Cir. Nov. 21, 2007) (applying learned intermediary doctrine to failure to warn claim brought under the OPLA).

Because the VAD is a prescription medical device, the learned intermediary doctrine applies. Under this doctrine, the manufacturer is "only under a duty to provide warning and instruction to the physician." *Yanovich*, 255 Fed. App'x at 970. The learned intermediary doctrine therefore bars a failure to warn claim unless the plaintiff establishes that the warnings to his physician were inadequate and that the physician did not have substantially the same information as the manufacturer, *i.e.*, the physician did not have independent knowledge of the risks associated with the device. *Id.*

Thus, to the extent Plaintiff's claim is based on a failure to warn her or Decedent directly, it is barred by the learned intermediary doctrine. Moreover, Plaintiff has not pleaded any allegations concerning the warnings provided to Plaintiff's implanting physician, nor the extent of that unidentified physician's knowledge regarding the risks of the VAD. Instead, Plaintiff merely alleges that the device was "defective due to inadequate warning and/or instruction." (Compl. ¶ 25.) Nor has Plaintiff pleaded what warnings she believes would have been appropriate or adequate. Finally, Plaintiff does not identify the particular risk that should have been communicated, nor that the Decedent experienced the same complication. Plaintiff's vague, generalized allegations do not survive an *Iqbal/Twombly* analysis, and Plaintiff's product liability claims should be dismissed accordingly.

D. The OPLA Abrogates Plaintiff's Common Law Claims

To the extent Plaintiff asserts common law claims for products liability (Count II) and punitive damages (Count III), they should also be dismissed because the OPLA is intended to "to abrogate all common-law product liability claims or causes of action." Ohio Rev. Code § 2307.71(B). The OPLA "explicitly eliminate[s] 'all common law product liability claims or causes

of action.'" *Wimbush v. Wyeth*, 619 F.3d 632, 639 (6th Cir. 2010) (quoting Ohio Rev. Code § 2307.71(B)). The OPLA "applies to any recovery of compensatory, punitive, or exemplary damages based on a product liability claim." *Tolliver v. Bristol-Myers Squibb, Co.*, No. 1:12 CV 00754, 2012 U.S. Dist. LEXIS 105518, at *5 (N.D. Ohio July 30, 2012). "The statute defines a 'product liability claim' as one 'that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question' allegedly resulting from a manufacturing or design defect, inadequate warning, or nonconformance with manufacturer representations." *Id.* (quoting Ohio Rev. Code § 2307.71(A)(13)). The OPLA applies to product liability claims brought against medical device manufacturers. *See, e.g.*, *Aaron*, 209 F. Supp. 3d at 1011-12; *see also* Ohio Rev. Code § 2307.71(A)(5).

It is not clear whether Plaintiff's product liability claim (Count II) is asserted as a common law or statutory claim, as Plaintiff makes only a fleeting reference to the OPLA in one paragraph. (*See* Compl. ¶ 29) ("As a direct and proximate result of the tortious conduct of all Defendants, their agents, servants and/or employees violated ORC §2307.72 through §2307.80."). Thus, to the extent Plaintiff's product liability claim is asserted under common law, it should be dismissed as abrogated by the OPLA. *See, e.g.*, *Miles v. Raymond Corp.*, 612 F. Supp. 2d 913 (N.D. Ohio 2009) ("[I]f the common law . . . claims asserted by Plaintiffs are covered by the statutory language abrogating common law product liability causes of action, those claims are extinguished."); *Favor v. W.L. Gore & Assocs.*, No. 2:13-cv-655, 2014 U.S. Dist. LEXIS 17134, at *14-15 (S.D. Ohio Feb. 11, 2014) (dismissing complaint because plaintiff failed to assert claims under OPLA and instead alleged common law claims).

III. THE COURT SHOULD DISMISS PLAINTIFF'S CLAIMS FOR WRONGFUL DEATH AND PUNITIVE DAMAGES DUE TO THE FAILURE OF PLAINTIFF'S PREDICATE CLAIMS.

"[A] wrongful death claim must be predicated upon a separate tort." *Biehl v. B.E.T., Ltd.*, No. 2:15-cv-2879, 2018 U.S. Dist. LEXIS 17125, at *30 (S.D. Ohio Feb. 2, 2018) (citation omitted), *aff'd*, 2018 U.S. App. LEXIS 29343 (6th Cir. Oct. 17, 2018); *see also Radous v. Emeritus Corp.*, No. 1:12-cv-319, 2013 U.S. Dist. LEXIS 43425, at *5 (N.D. Ohio Mar. 27, 2013) (recognizing that wrongful death claim is derivative). Similarly, Ohio law does not recognize punitive damages as an independent cause of action. *Thompson v. Sunbeam Prods.*, No. 2:10-cv-98, 2011 U.S. Dist. LEXIS 110677, at *3 n.1 (S.D. Ohio Sep. 28, 2011) (punitive damages "are simply a remedy for other claims"). For the reasons set forth above, *see* § I-II, *supra*, all of Plaintiff's underlying products liability claims fail. Consequently, the Court should dismiss Plaintiff's wrongful death cause of action and her claim for punitive damages.

IV. THE COURT SHOULD DISMISS PLAINTIFF'S CLAIM FOR PUNITIVE DAMAGES BECAUSE PLAINTIFF'S ALLEGATIONS ARE INADEQUATE AND BECAUSE, EVEN IF ADEQUATELY PLED, IT IS CATEGORICALLY PREEMPTED.

Even if Plaintiff's products liability claims were sufficient to survive a motion to dismiss (they are not), the Court should still dismiss Plaintiff's claim for punitive damages for two reasons. First, Plaintiff's allegations are insufficient to satisfy the punitive damages exception of the OPLA. Second, even if the claim were sufficiently pleaded, the OPLA's exception is legally invalid.

A. Plaintiff Failed to Plead Sufficient Facts to Satisfy the OPLA's Exception

Although the OPLA generally precludes punitive damages when the medical device at issue "was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the [FDA]," Ohio Rev. Code § 2307.80(C)(1)(a), punitive damages are permitted upon a showing "that the manufacturer fraudulently and in violation of

applicable regulations of the [FDA] withheld from the [FDA] information known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to the [FDA] information of that type." Ohio Rev. Code § 2307.80(C)(2). Here, Plaintiff fails to allege facts sufficient to meet this exception. Plaintiff's conclusory allegation that "Defendants knew that the Products were defective, . . . [and] willfully and knowingly withheld knowledge of the defect, malfunction or failure from the FDA" (Compl. ¶ 28) is not supported by any allegation that would permit the survival of a punitive damages request. *See Twombly*, 550 at 550.

B. The Exception in § 2307.80(C)(2) Is Legally Invalid.

Even if Plaintiff's allegations were sufficient to satisfy § 2307.80(C)(2), the exception is legally invalid because any such claim would be preempted by federal law. Interpreting a similar Michigan statute, the Sixth Circuit held that "state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004) (citation omitted). The reasoning in *Garcia* is equally applicable here, because Ohio law authorizes punitive damages in claims related to a drug or device is permitted "*only if* the FDA has made a finding of either fraud or misrepresentation." *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, MDL No. 1909, 2013 U.S. Dist. LEXIS 20706, at *61 (N.D. Ohio Feb. 13, 2013) (emphasis in original). Because such a claim would be preempted, Plaintiff cannot state a claim for punitive damages against Defendants. *See, e.g., Monroe v. Novartis Pharm. Corp.*, 29 F. Supp. 3d 1115, 1129-30 (S.D. Ohio 2014) (dismissing punitive damages claim on this basis).

CONCLUSION

Wherefore, Defendants respectfully request that the Court dismiss Plaintiff's Complaint in its entirety and grant such other relief as the Court deems just and proper.

Dated: January 20, 2020

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CERTIFICATE OF LR 7.1(f) COMPLIANCE

I hereby certify that this matter is on the administrative, standard, and unassigned track and the foregoing memorandum relating to a dispositive motion complies with Local Rule 7.1(f) because this matter is on the complex track and does not exceed twenty (20) pages.

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CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of January, 2020, I caused true and correct copies of the foregoing to be filed with the Court using the CM/ECF system and, further, caused true and correct copies to be served via electronic mail to the electronic mail address set forth below:

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